

IN THE CLAIMS:

Please amend the claims to have the status and content indicated in the following listing of claims, wherein any cancellation of claims is made *without prejudice*.

1. (Currently amended) A lyophilized composition comprising a physiologically active substance and a stabilizer, wherein the stabilizer is a recombinant or synthetic gelatin-like polypeptide comprising at least one stretch of 10 or more consecutive repeats of Gly-Xaa-Yaa triplets, wherein each of Xaa and Yaa is an amino acid, wherein at least 20% of the amino acids in the recombinant or synthetic polypeptide are present in the form of consecutive Gly-Xaa-Yaa triplets and wherein the recombinant or synthetic polypeptide has a calculated glass transition temperature of higher than 180 degrees Celsius as calculated using formula 8 and 9 in Y. Matveev et al. Food Hydrocolloids Vol. 11 no. 2, pp. 125-133, 1997. the following equations (8) and (9)

$$(8) \quad T_g^{-1} = \sum_{i=1}^{20} \phi_i T_{g,i}^{-1} \quad \text{wherein (9) } \phi_i = n_i \Delta V_i / \sum_{i=1}^{20} n_i \Delta V_i$$

wherein T_g is the glass transition temperature of the polypeptide, ΔV_i is the van der Waals volume of the i th amino acid residue, n_i is the number of amino acid residues of i th type per mole of polypeptide, $T_{g,i}$ is the partial increment of the T_g and the summations $i=1$ to 20 are the summations of the values for the partial values of T_g and ΔV of the separate amino acids as follows:

No.	Amino Acid	$T_{g,i}$ (Kelvin)	ΔV_i
1	Gly	599	47.3
2	Ala	621	64.4
3	Val	931	98.6
4	Leu	400	115.7
5	Ile	400	115.7
6	Phe	528	139.9
7	Pro	423	88.0
8	Trp	544	196.9

<u>9</u>	<u>Ser</u>	<u>311</u>	<u>66.1</u>
<u>10</u>	<u>Thr</u>	<u>321</u>	<u>88.9</u>
<u>11</u>	<u>Met</u>	<u>362</u>	<u>120.6</u>
<u>12</u>	<u>Asn</u>	<u>232</u>	<u>94.6</u>
<u>13</u>	<u>Gln</u>	<u>312</u>	<u>111.7</u>
<u>14</u>	<u>Cys-sh</u>	<u>418</u>	<u>82.2</u>
<u>15</u>	<u>Asp</u>	<u>672</u>	<u>80.1</u>
<u>16</u>	<u>Glu</u>	<u>487</u>	<u>97.2</u>
<u>17</u>	<u>Tyr</u>	<u>573</u>	<u>136.9</u>
<u>18</u>	<u>His</u>	<u>488</u>	<u>118.9</u>
<u>19</u>	<u>Lys</u>	<u>258</u>	<u>118.1</u>
<u>20</u>	<u>Arg</u>	<u>410</u>	<u>138.4</u>

▲

2. (Previously presented) A composition as in claim 1 wherein said recombinant or synthetic gelatin-like polypeptide has a molecular weight between 3,000 Dalton and 80,000 Dalton.
3. (Previously presented) A composition as in claim 1 wherein said recombinant or synthetic gelatin-like polypeptide has a molecular weight between 3,000 Dalton and 15,000 Dalton.
4. (Previously presented) A composition as in claim 1 wherein the glass transition temperature of the recombinant or synthetic gelatin-like polypeptide is higher than 190 degrees Celsius.
5. (Previously presented) A composition as in claim 1 wherein the recombinant or synthetic gelatin-like polypeptide has a bimodal molecular weight distribution.
6. (Previously presented) A composition as in claim 1 wherein the recombinant or synthetic gelatin-like polypeptide is free from helical structure.

7. (Previously presented) A composition as in claim 1 wherein the number of hydroxyproline residues in the recombinant or synthetic gelatin-like polypeptide is less than 5% of the total number of amino acid residues.

8. (Cancelled)

9. (Currently amended) Process for lyophilizing ~~compositions a composition, the process~~ comprising lyophilizing a composition comprising a physiological active substance and a stabilizer wherein the stabilizer is a recombinant or synthetic gelatin-like polypeptide comprising at least one stretch of 10 or more consecutive repeats of Gly-Xaa-Yaa triplets, wherein each of Xaa and Yaa is an amino acid, wherein at least 20% of the amino acids are present in the form of consecutive Gly-Xaa-Yaa triplets and less than 5% of the total number of amino acid residues are hydroxyproline residues and wherein said recombinant or synthetic gelatin-like polypeptide has a calculated glass transition temperature of higher than 180 degrees Celsius as calculated using formula 8 and 9 in Y. Matveev et al. Food Hydrocolloids Vol. 11 no. 2, pp. 125-133, 1997, the following formulae (8) and (9)

$$(8) T_g^{-1} = \sum_{i=1}^{20} \phi_i T_{g,i}^{-1} \quad \text{wherein (9) } \phi_i = n_i \Delta V_i / \sum_{i=1}^{20} n_i \Delta V_i$$

wherein T_g is the glass transition temperature of the polypeptide, ΔV_i is the van der Waals volume of the i th amino acid residue, n_i is the number of amino acid residues of i th type per mole of polypeptide, $T_{g,i}$ is the partial increment of the T_g and the summations $i=1$ to 20 are the summations of the values for the partial values of T_g and ΔV of the separate amino acids as follows:

No.	Amino Acid	$T_{g,i}$ (Kelvin)	ΔV_i
1	Gly	599	47.3
2	Ala	621	64.4
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<u>5</u>	<u>Ile</u>	<u>400</u>	<u>115.7</u>
<u>6</u>	<u>Phe</u>	<u>528</u>	<u>139.9</u>
<u>7</u>	<u>Pro</u>	<u>423</u>	<u>88.0</u>
<u>8</u>	<u>Trp</u>	<u>544</u>	<u>196.9</u>
<u>9</u>	<u>Ser</u>	<u>311</u>	<u>66.1</u>
<u>10</u>	<u>Thr</u>	<u>321</u>	<u>88.9</u>
<u>11</u>	<u>Met</u>	<u>362</u>	<u>120.6</u>
<u>12</u>	<u>Asn</u>	<u>232</u>	<u>94.6</u>
<u>13</u>	<u>Gln</u>	<u>312</u>	<u>111.7</u>
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<u>15</u>	<u>Asp</u>	<u>672</u>	<u>80.1</u>
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<u>19</u>	<u>Lys</u>	<u>258</u>	<u>118.1</u>
<u>20</u>	<u>Arg</u>	<u>410</u>	<u>138.4</u>

10. (Previously presented) A composition as in claim 2 wherein the glass transition temperature of the recombinant or synthetic gelatin-like polypeptide is higher than 190 degrees Celsius.

11. (Previously presented) A composition as in claim 3 wherein the glass transition temperature of the recombinant or synthetic gelatin-like polypeptide is higher than 190 degrees Celsius.

12. (Previously presented) A composition as in claim 2 wherein the recombinant or synthetic gelatin-like polypeptide has a bimodal molecular weight distribution.

13. (Previously presented) A composition as in claim 3 wherein the recombinant or synthetic gelatin-like polypeptide has a bimodal molecular weight distribution.

14. (Previously presented) A composition as in claim 4 wherein the recombinant or synthetic gelatin-like polypeptide has a bimodal molecular weight distribution.
15. (Previously presented) A composition as in claim 2 wherein the recombinant or synthetic gelatin-like polypeptide is free from helical structure.
16. (Previously presented) A composition as in claim 3 wherein the recombinant or synthetic gelatin-like polypeptide is free from helical structure.
17. (Previously presented) A composition as in claim 4 wherein the recombinant or synthetic gelatin-like polypeptide is free from helical structure.
18. (Previously presented) A composition as in claim 5 wherein the recombinant or synthetic gelatin-like polypeptide is free from helical structure.
19. (Previously presented) A composition as in claim 2 wherein the number of hydroxyproline residues in the recombinant or synthetic gelatin-like polypeptide is less than 5% of the total number of amino acid residues.
20. (Previously presented) A composition as in claim 3 wherein the number of hydroxyproline residues in the recombinant or synthetic gelatin-like polypeptide is less than 5% of the total number of amino acid residues.
21. (Previously presented) A composition as in claim 1 wherein the glass transition temperature of the recombinant or synthetic gelatin-like polypeptide is higher than 200 degrees Celsius.
22. (Previously presented) A composition as in claim 2 wherein the glass transition temperature of the recombinant or synthetic gelatin-like polypeptide is higher than 200 degrees Celsius.

23. (Previously presented) A composition as in claim 3 wherein the glass transition temperature of the recombinant or synthetic gelatin-like polypeptide is higher than 200 degrees Celsius.
24. (Previously presented) A composition as in claim 1 wherein the complete amino acid sequence of the recombinant or synthetic gelatin-like polypeptide is essentially similar to a region of the amino acid sequence of a native collagen.
25. (Previously presented) A composition as in claim 24 wherein the native collagen sequence is selected from the group consisting of natural human collagen amino acid sequences, non-human collagen amino acid sequences, rat collagen amino acid sequences, rabbit collagen amino acid sequences and mouse collagen amino acid sequences.
26. (Previously presented) A composition as in claim 24 wherein the complete recombinant or synthetic gelatin-like polypeptide has a calculated average glass transition temperature higher than the calculated average glass transition temperature of the complete native collagen by an amount selected from the group consisting of about 10 degrees Celsius, about 20 degrees Celsius, about 30 degrees Celsius and about 40 degrees Celsius.
27. (Previously presented) A composition as in claim 24 wherein the recombinant or synthetic gelatin-like polypeptide sequence has a measured glass transition temperature higher than the measured glass transition temperature of the native collagen by an amount selected from the group consisting of about 5 degrees Celsius, about 10 degrees Celsius and about 20 degrees Celsius.
28. (Previously presented) A composition as in claim 24 wherein the native collagen amino acid sequence has a calculated moving average glass transition temperature along the native collagen amino acid sequence with a value for the amino acid region of the native collagen of at least about 10 degrees Celsius higher than the calculated average collagen glass transition temperature of the complete native collagen and wherein, optionally, the native collagen is human collagen.

29. (Previously presented) A composition as in claim 24 wherein the recombinant or synthetic gelatin-like polypeptide has a molecular weight between 3,000 Dalton and 80,000 Dalton and the native collagen has a molecular weight between 10,000 Dalton and 300,000 Dalton.

30. (Previously presented) A composition as in claim 1 wherein the complete amino acid sequence of the recombinant or synthetic gelatin-like polypeptide comprises a repetitive sequence being a repeated unit sequence, the unit sequence being essentially similar to a region of a native collagen amino acid sequence.